EXHIBIT

A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SCOTT VINCENT SHAW, Individually, As Administrator of the Estate of EFFIE ELWINA SHAW, Deceased, and on Behalf of the Beneficiaries of the Estate, REX JOHNSON SHAW, SCOTT VINCENT SHAW, ELIZABETH DAWN SHAW FRANK, and ANNA MARIA SHAW ALLRED, Plaintiffs, vs. AMERIDOSE, LLC; ARL BIO PHARMA, INC., d/b/a ANALYTICAL RESEARCH LABORATORIES; GDC PROPERTIES MANAGEMENT, LLC; MEDICAL SALES MANAGEMENT, INC.; MEDICAL SALES MANAGEMENT SW, INC.; GREGORY CONIGLIARO; DOUGLAS CONIGLIARO; CARLA CONIGLIARO; BARRY CADDEN; LISA CONIGLIARO CADDEN; and GLENN A. CHIN Defendants.	)	CASE NO. _____

COMPLAINT AND JURY DEMAND

NOW COMES Plaintiffs, Scott Vincent Shaw, individually, as Administrator of the Estate of Effie Elwina Shaw, deceased, and on behalf of its beneficiaries, Rex Johnson Shaw, Scott Vincent Shaw, Elizabeth Dawn Shaw Frank and Anna Maria Shaw Allred, by and through undersigned counsel, and for their causes of action file this wrongful death complaint for damages against the above-named Defendants alleging the following:

INTRODUCTION

1. In 2012, a widespread outbreak of fungal meningitis injured people in more than 20 states and caused at least 55 deaths at the time of the filing of this Complaint. At a minimum,

more than 700 people have been diagnosed with meningitis and thousands more live in fear of contracting the disease and the prospect of suffering painful injuries, testing and treatment. This preventable outbreak originated from a medication compounded and distributed by Defendants and/or with Defendants' knowledge, or as a result of their negligent acts or omissions.

2. The Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") identified fungus in lots of the Defendants-supplied injectable steroids, specifically methylprednisolone acetate ("MPA") and other drugs. The FDA and CDC concluded that the MPA, which was compounded at Defendants' facilities, was the cause of the aforementioned injuries and death. Defendants' facilities were shamefully unsterile, and were the source of fungus that contaminated vials holding Defendants' compounded medications. Defendants' blatant disregard for even the most basic sterility obligations, their wanton disregard for the requirements of their licenses, their conscious disregard for safety standards, their deplorable facility conditions and blatant contempt for prior complaints, adverse events, and inspection findings, along with other Defendants' woefully insufficient testing, inadequate warning, overt misrepresentations, and knowing distribution of drugs compounded amidst such wrongful conduct, all led to a national epidemic of fungal meningitis.

3. Multiple vials of MPA, along with other medications developed at the Defendants' facilities have been recalled, but the recall was too late for Decedent Effie Elwina Shaw, and for many others who suffered serious, and catastrophic injuries or death.

PARTIES

4. Decedent, Effie Elwina Shaw (herein after "Mrs. Shaw" or "Decedent"), was a citizen and resident of Davidson County, North Carolina and lived at 1410 Farmer Road, Denton, North Carolina 27239 at the time of her death. Defendants are responsible for Mrs.

Shaw's death and the suffering she endured consciously before dying. Mrs. Shaw is survived by her husband and three adult children.

5. Plaintiff Scott Vincent Shaw is and was at all relevant times, a citizen and resident of Davidson County, North Carolina and lived at 395 Forrest Hills Estate, Denton, North Carolina 27239. Scott Vincent Shaw is the son and has been duly appointed Administrator of the Estate of Effie Elwina Shaw by The General Court of Justice, Superior Court Division, Davidson County, State of North Carolina. Plaintiff has filed proof of his authority as a Domiciliary Foreign Personal Representative in Suffolk County, Massachusetts Probate and Family Court and has gained authority over all property of the Decedent in the Commonwealth of Massachusetts. Plaintiff Scott Vincent Shaw brings this suit as Decedent's son and administrator of her estate.

6. Plaintiff Rex Johnson Shaw, residing at 1410 Farmer Road, Denton, North Carolina 27239, is the surviving spouse of Effie Elwina Shaw, deceased.

7. Plaintiff Elizabeth Dawn Shaw Frank, residing at 2339 Yates Road, Denton, North Carolina 27239, is the daughter of Effie Elwina Shaw, deceased.

8. Plaintiff Anna Maria Shaw Allred, residing at 1390 Spanish Drive, Asheboro, North Carolina 27205, is the daughter of Effie Elwina Shaw, deceased.

9. Defendant, Ameridose LLC ("Ameridose") is a Massachusetts limited liability company with a principal place of business at 203 Flanders Road, Westborough, Massachusetts 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, MA 01702.

Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director and Gregory Conigliaro is the Secretary and Director. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, MA 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC") is a Massachusetts limited liability company with a principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL BioPharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. The Chief Executive Officer and registered agent of ARL is Thomas Kupiec.

14. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is also the founder and a Manager of Ameridose and involved in Ameridose's day-to-day operations. Gregory Conigliaro is also Secretary and Director of MSM and MSMSW.

15. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Douglas Conigliaro is Director and President of MSM and MSMSW. Douglas Conigliaro provided advice, oversaw day-to-day operations and regularly appeared in the MSM/MSMSW facility.

16. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Carla Conigliaro is one of the Directors of NECC and the wife of Douglas Conigliaro.

17. Defendant Barry Cadden ("Barry Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Barry Cadden was at all relevant times, the President and Director of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by 247 CMR 2.00, and upon information and belief, compounded MPA at NECC. Barry Cadden was also a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.

18. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

19. Defendant Glenn A. Chin ("Glenn Chin") is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a

pharmacist at NECC. Glenn Chin, upon information and belief, compounded drugs, including MPA, at NECC.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

21. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

22. At all times relevant hereto, Defendants were engaged in the business of either developing, compounding, marketing, distributing, promoting and/or selling, directly or indirectly, or assisting Defendants with these activities, through third parties or other related entities, MPA and other drugs in the Commonwealth of Massachusetts, in interstate commerce, and from which they derived significant and regular income.

23. Defendants, except for ARL, have their principal places of business and/or residences in Massachusetts and are citizens of Massachusetts. Defendant ARL does business and has sustained contacts in Massachusetts sufficient to subject ARL to this Court's general and personal jurisdiction.

STATEMENT OF THE FACTS

A. RELEVANT BACKGROUND

24. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including North Carolina.

25. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry Cadden, and Lisa Cadden.

26. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden also was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.

27. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

28. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

29. At least until October 2012, Gregory Conigliaro was involved in co-managing the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC.

30. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC.

31. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC.

32. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

33. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

34. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief at the direction of the NECC principals, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

35. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalsalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

36. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

37. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW stated: "I didn't think there was any difference [between Ameridose and NECC]."

38. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to

the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

39. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

40. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

41. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

42. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

43. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust.***" (emphasis is original).

44. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the market today[.]**" (emphasis in original).

45. Upon information and belief, ARL provided sterility testing services and information to NECC for its compounded medications, including MPA.

46. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the results. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

47. GDC, which is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

48. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

49. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state …rules and regulations."

50. GDC maintained a high degree of control over the premises leased by NECC.

51. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed and/or distributed MPA. MPA is a steroid that is used, *inter alia*, to treat neck and back pain. MPA is administered via spinal-area injection to patients with neck and back pain.

52. GDC and Gregory Conigliaro knew that NECC was compounding MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

53. Until October 2012, NECC compounded MPA at its facility in Framingham, Massachusetts, and NECC sold MPA to healthcare providers in more than 20 states across the country.

54. On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") were notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

55. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

56. According to the CDC, symptoms for meningitis include the following: new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, slurred speech, and increased pain, redness or swelling at the injection site. Death may result from meningitis.

57. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

58. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

59. The FDA identified High Point Surgery Center in High Point, North Carolina as one of the healthcare facilities that received vials of MPA that were part of the September 2012 recall. High Point Surgery Center is also the location where Effie Elwina Shaw was injected with NECC's MPA.

60. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

61. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

62. In NECC's October 6, 2012, press release, NECC explained that "[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists until at least December 31, 2012. Lisa

Cadden also has voluntarily ceased her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacists since voluntarily ceasing their practice.

65. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

66. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

67. From May through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

68. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

69. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile."

ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

70. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

71. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

72. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.

73. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

74. ARL was well aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.

75. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

76. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

77. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

78. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

79. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

80. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

81. Other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.

82. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of MPA. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa

Cadden and Glenn Chin knew or should have known of these findings. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate those isolates and made no effort to identify those isolates. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

B. DEENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY

83. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug and Cosmetic Act, or related regulations.[1] The findings reveal repulsive conditions where bacteria and mold fester throughout the NECC facility and equipment.

[1] Plaintiffs are not asserting a private cause of action based on any FDA regulations.

84. In early October 2012, FDA investigators located fungal contamination in a sealed vial of MPA at NECC's facilities on GDC's property. FDA's findings prompted NECC to recall 17,676 single-dose vials of MPA.

85. Even though NECC recalled the MPA in early October, thousands of people at outpatient clinics and similar facilities in more than 20 states were injected with the steroid between July and September 2012.

86. The Massachusetts Department of Public Health (DPH) investigators, in collaboration with investigators from the U.S. Food and Drug Administration (FDA), investigated NECC and released preliminary findings on October 23, 2012.

87. As an initial matter, the DPH: "Upon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."

88. In its preliminary findings the DPH found: "During the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy." The DPH noted:

1. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

    a. Lot *06292012@26* was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.

    b. Lot *08102012@51* was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

2. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operating

Procedures: Examination of NECC records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

3. NECC did not conduct proper validation of autoclaves pursuant to USP 797: NECC failed to test their autoclaves to ensure proper function.

4. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot *08102012@51.*

5. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 979. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

6. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

7. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: "A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

89. Surface samples from NECC's "clean" rooms revealed bacterial and mold, as did various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling throughout the facility revealed mold and bacteria. Dozens of results exceeded the "action level." "There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacterial and mold) from the facility."

90. Environmental monitoring procedures require sampling. Records showed mold and bacterial. "These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has

no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

91. FDA observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products. FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.

92. The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with law levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.

93. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC's facility. As FDA noted in its inspection, "The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

94. FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions. FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within

Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

95. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one it repeatedly represented to customers was "state-of-the-art" and used to produce "highest quality compounded medications."

96. MSM and/or MSMSW marketed and Ameridose and/or distributed the products compounded in such deplorable conditions.

C. DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS

97. Defendants effectively ignored dozens of complaints from as early as April 1999. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. FDA notified the state pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acetate, which is the same steroid that caused the current outbreak.

98. In 2004, an inspector report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid.

99. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

100. NECC and other Defendants solicited out-of-state prescriptions for office use and used unapproved forms. NECC and other Defendants were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

D. DEFENDANTS WANTONLY EXPOSED DECEDENT TO THIS TOXIN

101. In 2012, Defendants caused numerous vials of methylprednisolone acetate contaminated with fungi and other contaminants to be shipped to High Point Surgery Center in High Point, North Carolina. Upon information and belief, Ameridose distributed these vials to High Point Surgery Center on behalf of NECC.

102. On or about April 26, 2012, Decedent, Effie Elwina Shaw, was a patient at High Point Surgery Center in High Point, North Carolina, where she was administered an interlaminar lumbar epidural steroid injection of 80 mg of methylprednisolone acetate compounded by NECC.

103. On or about June 1, 2012, Mrs. Shaw received a second epidural steroid injection of 160 mg of methylprednisolone acetate compounded by NECC, at High Point Surgery Center in High Point, North Carolina.

104. On or about August 28, 2012, Mrs. Shaw received a third epidural steroid injection of 160 mg of methylprednisolone acetate compounded by NECC, at High Point Surgery Center in High Point, North Carolina.

105. Unknown to Mrs. Shaw, the methylprednisolone acetate that was injected into her spine on or about August 28, 2012 was contaminated with a fungus. The lot that contained the vial of MPA administered to Mrs. Shaw was recalled approximately one month after it had been injected into her body.

106. Soon after her August 28, 2012 MPA injection, Mrs. Shaw became ill and developed nausea, headache, and body aches. On September 18, 2012 she saw a physician's assistant who instructed her to follow up about her condition, and later that same day, Mrs. Shaw was emergently transported by ambulance to High Point Regional emergency room.

107. At that time, Mrs. Shaw had constant pain, nausea, headache, body aches, and fever. Many Physicians saw Mrs. Shaw during this time; they performed tests, prescribed medications and attempted to determine the cause of Mrs. Shaw's illness. Mrs. Shaw was admitted to the hospital as her condition deteriorated. Mrs. Shaw exhibited symptoms consistent with meningitis, was ultimately diagnosed with fungal meningitis, and was treated accordingly during her hospitalization. Mrs. Shaw was hospitalized until her death on October 19, 2012. From the time of her illness to her death, she experienced extreme conscious physical pain and mental suffering. She died as a result of the Defendants' grossly negligent misconduct, acts and omissions.

108. As of February 2013, there have been hundreds of fungal meningitis cases and infections associated with the administration of contaminated methylprednisolone acetate compounded by Defendants, with 55 deaths reported nationwide.

109. On December 20, 2012, CDC issued a Health Alert Network notice providing updated guidance and information about the ongoing multistate outbreak of fungal infections attributed to contaminated methylprednisolone acetate. In summary, the notice disclosed that many patients who received injections of the contaminated methylprednisolone acetate have developed localized spinal or paraspinal infection, including epidural abscess, phlegmon, arachnoiditis, discitis, and vertebral osteomyelitis.

110. Defendants and their agents at all times were expected to provide proper maintenance, oversight, security and control of its laboratory, facilities, distribution facility and other units. Defendants were at all times under a duty to maintain procedures that protect patients and end consumers of the products Defendants marketed, sold, tested and/or distributed from infections and medical conditions through contaminated steroid medications or other medications.

111. Upon information and belief, the contaminated steroid medication injected into Decedent's body was marketed, sold, compounded, tested and/or distributed by Defendants and Decedent was injured and died as a result of their wrongful conduct.

112. The products ingredients were obtained from other entities whose identities are not yet known.

COUNT I

NEGLIGENCE

(Against All Defendants)

113. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

114. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, Defendants owed a duty to the Decedent Mrs. Shaw to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to the Decedent.

115. Specifically, but without limitation:

a. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent

a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Decedent a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

116. Defendants breached those duties and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Decedent. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through its supervisors, staff and agents engaged in designing, compounding, sales, testing, marketing and distributing MPA in a negligent manner.

117. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test, and distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Decedent.

118. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Decedent by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

119. The negligence of Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin was a proximate cause of Decedent's death.

120. Decedent was exposed to fungal meningitis through NECC's contaminated steroid vial that was injected into her on August 28, 2012.

121. As a direct and proximate result of the negligence of Defendants, and being injected with a contaminated dose of methylprednisolone acetate, Mrs. Shaw suffered injuries, conscious pain and suffering, emotional distress, economic loss and death.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II

NEGLIGENCE PER SE

(Against All Defendants)

122. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

123. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

124. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties

owed to Decedent by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

125. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

126. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mrs. Shaw suffered injuries, conscious pain and suffering, emotional distress, economic loss and death.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III

NEGLIGENT SUPERVISION

(Against All Defendants)

127. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

128. Defendants Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Decedent and others who received the compounded medications.

129. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

130. The Defendants knew, or should have known, that the employee or agent did not follow proper procedures and knew or should have known of the risks created by failing to do so.

131. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Decedent, Mrs. Shaw.

132. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated methylprednisolone acetate, Mrs. Shaw suffered injuries, conscious pain and suffering, emotional distress, economic loss and death.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IV

BREACH OF IMPLIED WARRANTY

(Against All Defendants Except ARL and GDC)

133. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

134. The contamination of NECC and other Defendants' methylprednisolone acetate was present at the time the drug left the facilities' possession and control.

135. The contaminated methylprednisolone acetate was not altered in any way after it was sold by NECC and other Defendants, and the drug was used as intended.

136. Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the implied warranty of merchantability by failing to use reasonable care in compounding, testing, marketing and/or distributing methylprednisolone acetate. GDC failed to adequately maintain the facility where the aforementioned compounding took place.

137. The breaches by Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin of the implied warranties of merchantability were a proximate cause of Decedent's injuries and death.

138. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated methylprednisolone acetate, Mrs. Shaw suffered injuries, conscious pain and suffering, emotional distress, economic loss and death.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count IV of this Complaint, in an amount that will justly compensate for the

damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT V

PUBLIC NUISANCE

(Against Barry Cadden, Gregory Conigliaro and GDC)

139. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

140. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

141. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

142. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

143. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

144. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

145. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

146. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC caused Mrs. Shaw's injury and death.

147. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mrs. Shaw suffered injuries, conscious pain and suffering, emotional distress, economic loss, damages and died.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count V of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VI

DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS[2]

(Against All Defendants)

148. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

149. Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

150. Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

151. As described herein, Defendants represented that their product had characteristics, uses and benefits that it did not have.

[2] Plaintiffs have provided written notice under M.G.L. c. 93A, however, 30 days has not yet passed, therefore, Plaintiffs will amend to add a specific reference to a violation of M.G.L.c.93A once the required timeframe has passed.

152. As describe herein, Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

153. Defendants failed to provide accurate disclosures of all material information before Decedent and her providers transacted to use Defendants' product.

154. Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Mrs. Shaw, constituting a violation of the Act.

155. Defendants'' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

156. Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

157. Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

158. Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Mrs. Shaw.

159. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Mrs. Shaw, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein

160. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally Defendants were unethical and unscrupulous, and caused substantial injury to consumers. Defendants engaged in an unconscionable actions and course of action.

161. Defendants willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

162. Defendants are liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count VI of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VII

WRONGFUL DEATH CLAIM

163. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

164. Plaintiffs, individually and for the benefit of all wrongful death beneficiaries, sue pursuant to the Wrongful Death Act and seeks full value of Decedent Effie Elwina Shaw's life.

165. The conduct described herein was caused by Defendants' and their agents' and servants' wrongful acts, neglect, carelessness, unskillfulness, and default.

166. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages as described with particularity herein.

167. Plaintiffs seek damages for the fair monetary value of the Decedent's injuries, physical conscious pain and suffering and mental and emotional anguish, the value of the Decedent to each of the Plaintiffs, including but not limited to compensation for the loss of the reasonably expected net income, services, protection, care, assistance, society, companionship, comfort, guidance, counsel and advice of the Decedent. Plaintiffs seek recovery for the reasonable medical and funeral expenses of the Decedent.

168. Defendants' willful, wanton, and reckless acts and omission and gross negligence caused Decedent's death and warrant the estate recovering punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count VII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. Economic and non-economic damages and damages for pain and suffering and loss of life in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory and other damages according to proof;

3. For punitive damages as allowed by law;

4. For an award of attorneys' fees and costs;

5. For prejudgment interest and the costs of suit; and

6. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: June 26, 2013.

Respectfully Submitted,

PLAINTIFF SCOTT VINCENT SHAW,

By His Attorneys,

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